PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Jill McFadden et al.	Confirmation No.:	2472
Serial No.:	09/097,023	Examiner:	Elizabeth Moulton
Filing Date:	June 12, 1998	Group Art Unit:	3767
Docket No.:	1001.1566101	Customer No.:	28075
For:	CATHETER WITH KNIT SECTION		

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

CERTIFICATE FOR ELECTRONIC TRANSMISSION:
The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 8th of April 2009.

By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sir:

Pursuant to 37 C.F.R. § 41.37, Appellants hereby submit this Appeal Brief in furtherance of the Notice of Appeal filed on November 20, 2008 and the Notice of Panel Decision from Pre-Appeal Review dated January 14, 2009, setting a one-month response period ending February 14, 2009.

Permission is hereby granted to charge the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of $540.00 to Deposit Account No. 50-0413.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Target Therapeutics, Inc., a corporation organized and existing under and by virtue of the laws of Delaware, and having a business address of 47201 Lakeview Boulevard, Fremont, CA 94357. An assignment from the inventors, Jill M. McFadden, Earl Bardsley and Robert Garabedian, conveying all right, title and interest in the invention to Target Therapeutics, Inc. has been recorded at Reel 009458, Frame 0534. Target Therapeutics, Inc. is a subsidiary of Boston Scientific Corporation.

II. RELATED APPEALS AND INTERFERENCES

A Notice of Appeal was previously filed in the present application on March 22, 2002. An Appeal Brief was submitted on May 22, 2002, and thereafter the Examiner withdrew the finality of the rejections in the application and presented new grounds for rejection of the claims. Therefore, the Examiner never submitted a written answer to the Appeal Brief, thus dismissing the Appeal from the appeal process.

Thereafter, another Notice of Appeal was filed in the present application on March 16, 2005. An Appeal Brief was submitted on May 16, 2005, to which An Examiner's Answer was mailed on July 26, 2005. Thereafter, A Reply Brief was filed on September 20, 2005. An Amended Appeal Brief was submitted on September 15, 2006 to correct an error identified in the Appeal Brief submitted on May 16, 2005. A Decision on Appeal was issued on September 19, 2007, in which the rejection of the then-pending claims was affirmed-in-part. Prosecution was then reopened with a new non-final Office Action.

III. STATUS OF CLAIMS

The application includes claims 1-63. Claims 1-50 and 53-63 have been cancelled from the application. Claims 51 and 52 stand finally rejected under 35 U.S.C. §103(a) as being unpatentable over Samson, U.S. Patent No. 5,702,373, in view of Andersen et al., U.S. Patent No. 5,662,713.

Claims 51 and 52 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

A Response After Final was filed on September 22, 2008, in which no claim amendments were made, but all pending claims, including updated status identifiers, were presented in a clean version along with accompanying remarks requesting reconsideration in response to a Final Office Action mailed July 29, 2008. An Advisory Action was mailed on October 10, 2008, stating the request for reconsideration was considered, but failed to place the application in condition for allowance. Appellant filed a Notice of Appeal concurrently with a Pre-Appeal Brief on November 20, 2008. A Notice of Panel Decision from Pre-Appeal Brief Review was mailed on January 14, 2009, stating that the application remains under appeal because there is at least one actual issue for appeal.

V. SUMMARY OF CLAIMED SUBJECT MATTER[1]

The invention relates to a catheter having a knit section. (Specification, lines 10 and 11 of page 1).

Turning now to the claims, independent claim 51 is directed to a catheter [Ref. 100] comprising an elongate tubular member having a proximal end, a distal end and a passageway defining a lumen extending between those ends (Specification, at lines 24-28; FIG. 1). The elongate tubular member comprises a relatively stiff proximal segment [Ref. 106, 124] including an inner proximal liner [Ref. 212], an outer proximal cover [Ref. 214], and a braid [Ref. 210] interposed between the inner proximal liner and the outer proximal cover (Specification, at lines 1-12 of page 10; FIGS. 1, 2, 5). The elongate tubular member also comprises a relatively flexible distal segment [Ref. 102, 122] comprising a knit tubular member [Ref. 128] and an inner tubular liner [Ref. 126] in coaxial relationship with the knit tubular member (Specification, at lines 10-14 of page 6; FIGS. 1, 2, 3). The knit tubular member is formed from a single strand [Ref. 134] forming a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand (Specification, at lines 3-16 of page 8; FIG. 4). The knit tubular member is generally not radially expandable (Specification, at lines 17-20).

Independent claim 52 is directed to a catheter [Ref. 100] comprising an elongate tubular member having a proximal end, a distal end and a passageway defining a lumen extending between those ends (Specification, at lines 24-28; FIG. 1). The elongate tubular member comprises a relatively stiff proximal segment [Ref. 106, 124] including an inner proximal liner [Ref. 212], an outer proximal cover [Ref. 214], and a coil [Ref. 216] interposed between the

[1] The references to the specification and drawings provided herein are only illustrative and not limiting in any way.

inner proximal liner and the outer proximal cover (Specification, at lines 1-12 of page 10; FIGS. 1, 2, 6). The elongate tubular member also comprises a relatively flexible distal segment [Ref. 102, 122] comprising a knit tubular member [Ref. 128] and an inner tubular liner [Ref. 126] in coaxial relationship with the knit tubular member (Specification, at lines 10-14 of page 6; FIGS. 1, 2, 3). The knit tubular member is formed from a single strand [Ref. 134] forming a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand (Specification, at lines 3-16 of page 8; FIG. 4). The knit tubular member is generally not radially expandable (Specification, at lines 17-20).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 51 and 52 are unpatentable under 35 U.S.C. §103(a) over Samson, U.S. Patent No. 5,702,373, in view of Andersen et al., U.S. Patent No. 5,662,713.

VII. ARGUMENT

1. Claims 51 and 52 are patentable over Samson, U.S. Patent No. 5,702,373, in view of Andersen et al., U.S. Patent No. 5,662,713.

Claims 51 and 52 stand rejected under 35 USC §103(a) as being unpatentable over Samson (U.S. Patent No. 5,702,373) in view of Andersen et al. (U.S. Patent No. 5,662,713). Appellants respectfully traverse this rejection, asserting a *prima facie* case of obviousness has not been established.

Independent claim 51 recites:

> 51. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:
>
> a relatively stiff proximal segment including an inner proximal liner, an outer proximal cover, and a braid interposed between the inner proximal liner and the outer proximal cover; and
>
> a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a single strand, wherein the single strand forms a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand;
>
> wherein the knit tubular member is generally not radially expandable.

"All words in a claim must be considered in judging the patentability of that claim against the prior art." M.P.E.P. §2143.03, quoting *In re Wilson*, 424 F.2d 1382, 165 USPQ 494, 496 (CCPA 1970). Nowhere do Samson or Andersen et al., either alone or in combination, teach or suggest a knit tubular member formed from a single strand forming a plurality of up loops and a plurality of down loops interlocking with the plurality of up loops, wherein the knit tubular member is generally not radially expandable, as currently claimed. Independent claim 52 also includes similar limitations.

Appellants assert that Samson does not teach a knit as recited in the claims. In formulating the rejection, the Examiner asserts that Ref. 244 of Samson is a knit tubular member. See FIG. 7 of Samson. Appellants respectfully disagree. Samson expressly teaches that the component denoted with reference number 244 is an inner braid of the catheter shown in FIG. 7. See Samson, at column 13, lines 45-61.

Samson is quite clear when describing a braid as indicated by the description when it is stated:

> Whenever I use the term "braid" herein, I mean tubular constructions in which the ribbons making up the construction are woven in an in-and-out fashion as they cross to form a tubular member defining a single lumen. The braids may be made up of a suitable number of ribbons, typically six or more.

Samson, at column 12, lines 15-20 (emphasis added). Thus, the inner braid of Samson, identified as Ref. 244, cannot be equated to the knit tubular member formed from a single strand forming a plurality of up loops and a plurality of down loops interlocking with the plurality of up loops, as currently claimed. The braid of Samson includes a plurality of ribbons making up the construction which are woven in an in-and-out fashion as they cross one another. In other words, the plurality of ribbons making up the braid of Samson are interwoven in a helical arrangement. Dissimilarly, as recited in claims 51 and 52, the claimed knit tubular member is formed of a single strand forming a plurality of up loops and a plurality of down loops. Up loops of the single strand are interlocked with down loops of the single strand to form the knit tubular member from the single strand. In the braid construction taught in Samson, a ribbon of the braid is not interlocked with another portion of the same ribbon, but rather a ribbon crosses over other ribbons of the braid.

Furthermore, Appellants assert Andersen et al. fail to teach a knit tubular member, as currently claimed, which is generally not radially expandable. Instead, Andersen et al., which

the Examiner relies on for its teaching of a knit made of a single fiber, teach a stent for reinforcement of the lumen of a peristaltic organ, such as the esophagus. Andersen et al. teach the stent is formed by knitting a wire into a pattern of overlapping loops such that in a relaxed state each row of loops may shift axially relative to and independent of the rows on either side accommodating peristalsis of the organ. See Andersen et al., at Abstract. This movement allows the stent to be placed into the lumen of a peristaltic organ without the stent migrating within the organ. Thus, Andersen et al. need the stent to be capable of expansion and contraction in order for the device to function as intended. Andersen et al. teach at column 3, line 65 through column 4, line 7:

> The rows of loops of the stent shift axially with elastic deformation of the wire of the loops so that the separation of the heads increases to a loop lengths l_1, as shown in FIG. 1e. In the region of maximum expansion 150, the length of each portion of the esophagus returns to its rest length, but the diameter is extended. The knit loops of the stent can widen, as shown in FIG. 1f, to accommodate this extension. Returning again to considering any peristaltic organ, the organ contracts (c of FIG. 1c) to compress a region.

FIG. 1c of Andersen et al. has been reproduced below to facilitate the discussion.

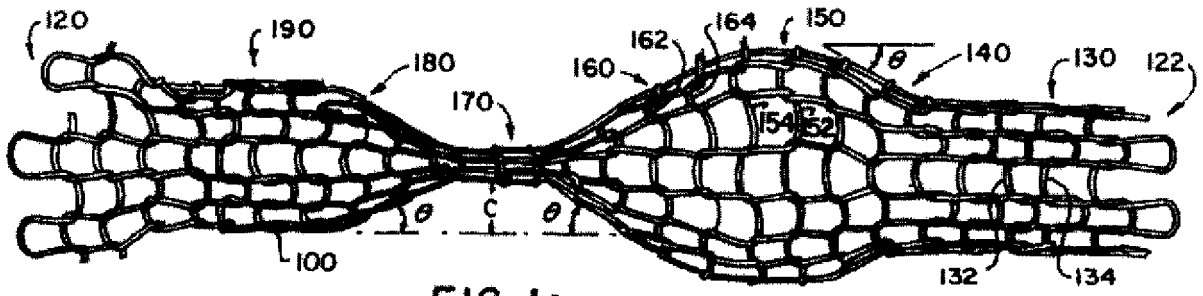

FIG. 1c

Andersen et al. intend the stent to radially expand and contract as shown in Figure 1c above. Further, while FIG. 9 of Andersen et al. shows the stent in a delivery position while disposed within a catheter, this is for the delivery of the stent to the desired location. Once the stent is

deployed from the delivery catheter, the stent radially expands. Thus the stent is indeed expandable, as this feature is necessary for the stent to function properly as discussed in Andersen et al. Andersen et al. teach away from the claimed invention. Section 2141.02 VI of the Manual of Patent Examining Procedure states, "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984)." The stent of Andersen et al. necessarily must be radially expandable in order to allow movement of the stent in a peristaltic organ without the stent migrating within the organ.

Furthermore, in formulating the rejection the Examiner asserts, "It would have been obvious to one of ordinary skill in the art at the time the invention was made to form a knit from a single strand as taught by Andersen." The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006), "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". Emphasis added; see page 14 of the April 30, 2007 decision. The Court further stated, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." See page 14 of the April 30, 2007 decision. The Examiner has failed to provide an articulated reasoning as to why one of skill in the art would modify the braid 244 of Samson with the esophageal stent of Andersen et al.

Appellants disagree with the suggested combination proposed by the Examiner, asserting that the Examiner's suggestion cannot be attained without following an impermissible hindsight analysis. The Federal Circuit has recently reaffirmed that a flexible application of a Teaching,

Suggestion, Motivation (TSM) Test is an effective means to prevent hindsight and focuses on evidence before the time of invention. The Federal Circuit stated "As this court has explained, however, a flexible TSM test remains the primary guarantor against a nonstatutory hindsight analysis." *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008).

Appellants assert that there is no rationale for combining the expandable esophageal stent of Andersen et al. in the catheter construction taught in Samson. Given the significantly different natures and desired results of the cited references, Appellants assert that it is only by applying impermissible hindsight using the instant application as a roadmap could the braid of the catheter of Samson be modified with the expandable stent of Andersen et al. as asserted by the Examiner. See for example, *Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004): The "as a whole" instruction in Title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention).

To ensure that the invention is considered "as a whole" the Federal Circuit requires "a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to

make the new combination" (*Ruiz v. A.B. Chance Co.*, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004 citing *In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998); emphasis added). The Federal Circuit has made it clear that this showing of motivation to combine two or more references must be "clear and particular" (See for example, *Winner International Royalty Corp. v. Wang*, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000)). No such showing has been established with the cited combination of references.

Thus, it is unclear why one of ordinary skill in the art would be motivated to combine the teaching of Samson and Andersen et al., as Samson is not believed to teach a knit. Even if one were to combine the teachings of Samson and Andersen et al., one would not arrive at the device as claimed. For at least these reasons a *prima facie* case of obviousness has not been established.

2. Conclusion.

For the reasons stated above, the rejections of claims 51 and 52 under 35 U.S.C. §§103(a) should be reversed.

Respectfully submitted,

Jill M McFadden et al.

By their attorney,

Date: 4/8/09

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VIII. CLAIMS APPENDIX

51. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:

a relatively stiff proximal segment including an inner proximal liner, an outer proximal cover, and a braid interposed between the inner proximal liner and the outer proximal cover; and

a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a single strand, wherein the single strand forms a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand;

wherein the knit tubular member is generally not radially expandable.

52. A catheter comprising an elongate tubular member having a proximal end, a distal end, and a passageway defining a lumen extending between those ends, said elongate tubular member comprising:

a relatively stiff proximal segment including an inner proximal liner, an outer proximal cover, and a coil interposed between the inner proximal liner and the outer proximal cover; and

a relatively flexible distal segment comprising a knit tubular member and an inner tubular liner in coaxial relationship with the knit tubular member, wherein the knit tubular member is formed from a single strand, wherein the single strand forms a plurality of up loops and a plurality of down loops, wherein the plurality of up loops of the single strand interlock with the plurality of down loops of the single strand;

wherein the knit tubular member is generally not radially expandable.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

None.